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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,079	05/09/2001	Steven G. Reed	210121.426C1.1	5270

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,079

Applicant(s)

REED ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1,7,9-11,13,14,17 and 19-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8, 12, 15- 16, 18 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 10. 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Claims 1-36 are pending in the application. Applicant's election of Group II claims 2-8, 12-16, 18 and 35-36 (polypeptide) with respect to SEQ.ID.NO: 195 in paper # 10 is acknowledged. Claims 2-6, 8, 12, 15- 16, 18 and 36 are drawn to polypeptide including the elected species SEQ.ID.NO: 195 under examination. Claims 7,13-14 and 35 are drawn to non-elected invention (SEQ.ID.NO: 36, 39, 52, 85-87,144 and 211) and therefore, have been withdrawn from consideration from elected group II.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, Claims 1, 9-11, 17, 19-34 have been withdrawn from withdrawn from consideration from non-elected groups I, III-VIII.

Claims 2-6, 8, 12, 15- 16, 18 and 36 are under examination

1, 7, 9-11, 13-14, 17 and 19-35 are withdrawn from consideration.

Priority

2. This application is a CIP of 09/794,764 02/26/2001
and is a CIP of 09/737,178 12/13/2000 ABN
and is a CIP of 09/685,436 10/10/2000 ABN
and is a CIP of 09/656,688 09/07/2000 ABN
and is a CIP of 09/605,724 06/27/2000 ABN
and is a CIP of 09/569,098 05/10/2000
and is a CIP of 09/528,784 03/17/2000 PAT 6,451,315
and is a CIP of 09/286,488 04/05/1999
and is a CIP of 08/990,571 12/11/1997 PAT 6,214,971

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and is a CIP of 08/845,258 04/24/1997 PAT 6,183,976

and is a CIP of 08/723,142 10/01/1996 PAT 6,306,396

Examiner has reviewed all the priority applications and found that SEQ.ID.NO: 195 was disclosed in the earlier filed application 09/794,764 02/26/2001 and therefore, claims 2, 12, 18 gets priority as of 02/26/2001

Information Disclosure Statement

3. Information Disclosure Statement and Supplemental Information Disclosure Statement filed on 1/16/02 and 8/20/02 (Papers # 6 and 10) is acknowledged and a signed copy is attached to this Office action (Paper No # 11).

Specification - Informalities

4. Claims should begin with "I claim" or "we claim" or "What is claimed is".

Applicant is advised to update the status of pending U.S. applications in the first page of the Specification.

Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 2, 12, 16, 18 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising SEQ.ID.NO 195, a fusion protein comprising SEQ.ID.NO: 195 and a composition comprising SEQ.ID.NO: 195 does not reasonably provide enablement for an isolated polypeptide comprising at least 70% and 90% sequence identity with SEQ.ID.NO 195, a fusion protein and a composition comprising said polypeptide (i.e., at least 70%, and 90% sequence identity with SEQ.ID.NO 195). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Scope of enablement requires that the specification teach those in the art to make and use the invention commensurate with the scope of the claim without undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification is not enabled for polypeptides, fusion proteins and compositions which have an amino acid 70% and 90% sequence identity with SEQ.ID.NO 195 because it is unclear to one skilled in the art what sequences are embraced by the claim. If it is unclear to one skilled in the art what sequences are embraced by a claim which is based on a specification to determine percent homology/identity/similarity, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

Applicant has not set forth which amino acid (s) deleted or inserted or substituted in the polypeptide SEQ.ID.NO 195. After these alterations or modifications whether the

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polypeptide still retain the activity as presently claimed is not set forth clearly in the specification.

The specification provides guidance and direction with regard to an isolated polypeptide SEQ.ID.NO 195 (page 47, lines 10-11) which is designated as BMNI 17-4 comprising 26 amino acids. However, there is no guidance or directions on how to make and use polypeptides which have an amino acid 70% and 90% sequence identity with SEQ.ID.NO 195 by deletion or substitution of one or more amino acid residues in the amino acid sequence of B.microti. Additional experimentation is necessary in order to make and use of said polypeptides.

It is well known that proteins, for example, that even a single amino acid change can destroy the function of the biomolecule. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity/utility are limited in protein and the result of such modifications is unpredictable based on the instant disclosure. Houghten et al. (Vaccines, 1986, Edited by Fred Brown: Cold Spring Harbor Laboratory) teach that changes/modifications (addition, substitution, deletion or inversion) of one or more amino acids in a polypeptide will alter antigenic determinants and therefore affect antibody production (p. 21) as well as antibody binding. Houghten et al. also teach that "...combined effects of multiple changes in an antigenic determinant could result in a loss of [immunological] protection." And "A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies..."

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(p. 24). Houghten et al. teach that point mutations at one key antigen residue could eliminate the ability of an antibody to recognize this altered antigen (p. 24). It is not always possible to make the variants that retain immunodominant regions and immunological activity if the regions have been altered. Therefore, an isolated polypeptide comprising at least 70% and 90% sequence identity with SEQ.ID.NO 195 would result in a peptide without any function.

Claim Rejections - 35 USC 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3-6, 8, 15-16, 18 and 36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected as being vague and indefinite. It is not clear what is the amino acid sequence of B.microti antigen, which contains an isolated antigenic epitope comprising the amino acid sequence X1-X5-Ser---.

Claim 36 is rejected as being vague in reciting "diagnostic kit." Is this kit for detecting B.microti infection or something else?

Claim Rejections - 35 USC 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.\

8. Claims 2, 12, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lodes et al (EPO 834567, published in 4/8/1998).

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Claims are directed to an isolated polypeptide, fusion protein and composition comprising SEQ.ID.NO: 195 and antigenic epitopes, fusion protein, kit and compositions comprising the same.

Lodes et al disclose an isolated polypeptide SEQ.ID.NO: 53 which contains an isolated polypeptide comprising SEQ.ID.NO: 195 (100% sequence alignment with SEQ.ID.NO: 53 from position 218-243), fusion proteins and composition comprising the same (claims and pages 101-102 of patent).

Claims 3-6, 8, 12, 15-16 and 36 also get the same priority date if applicant amends the claims with respect to SEQ.ID.NO: 195.

9. Claims 3-6, 8 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tetzlaff et al 1990 Molecular and Biochemical Parasitology 40:183-192.

Claims are drawn to an isolated epitope of B.microti antigen comprising the amino acid sequence X1-X5-Ser ---, and composition comprising the same.

Tetzlaff et al 1990 et al disclose clone Bm13 virulent B.microti (see figure 3) and its immunodominant regions (see figures 4 and 5 and page 189, left column).

Characteristics such as amino acid sequence would be inherent in the preparations (clone Bm13) of Tetzlaff et al because the recombinant clone Bm13 is from B. microti and its product (i.e., polypeptide) is identified by immunoblot using specific sera as shown in figure 4. The protein product encoded by Bm13 contains several epitopes as antibodies recognized 54kD protein. In the absence of evidence to the contrary the disclosed prior art protein comprises the claimed B.microti antigen and its epitopes anticipates the claimed invention. Since the Office does not have the facilities for examining and comparing applicants' claimed antigen with epitopes with the prior art B.microti antigen and epitopes, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best,

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562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

10. Claims 3-6, 8, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al 1991 (J.Clin.Microbiol, 29:2779-2783).

Claims are drawn to an isolated epitope of B.microti antigen comprising the amino acid sequence X1-X5-Ser---- and composition comprising the same.

Anderson et al disclose an isolated B.microti antigen, which contains the claimed epitopes. Applicant's use of the open-ended term " B.microti antigen comprising" would read on the Anderson et al's B.microti antigen. Characteristics such as amino acid sequence would be inherent in the preparations of Anderson et al because B. microti infected antigen contains several polypeptides with several epitopes. In the absence of evidence to the contrary the disclosed prior art anticipates the claimed invention. Since the Office does not have the facilities for examining and comparing applicants' claimed antigen with epitopes with the prior art B.microti antigen, the burden is on applicant to show a novel or unobvious difference between the between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Status of Claims

11. Claims 2- 6, 8, 12, 15-16, 18 and 36 are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

10/15/02



MARK NAVARRO
PRIMARY EXAMINER